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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,944	12/16/2004	Takashi Narui	262584US0PCT	4916

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/516,944	NARUI ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-16-04, 3-25-09, 4-24-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on January 29, 2009 is acknowledged. Claims 1-9 have been cancelled. Claims 10-18 are newly presented and are now under prosecution in this application.

Information Disclosure Statement

Receipt of the Information Disclosure Statements file on March 25, 2009 and April 24, 2009 is acknowledged. Signed copies are attached to this office action.

Regarding the Information Disclosure Statement filed on December 16, 2004, a signed copy has been attached to this office action. It is additionally noted that many of the references which were not originally submitted with English abstracts, thereby allowing the Examiner to ascertain there relevance to the instantly claimed invention, are now applied in the rejections below.

Any documents submitted without an English translation have been and will be considered to the extent that the Examiner can read and understand the language of the document.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants cancellation of claims 1-9.

The rejection of claims 5 and 7-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants cancellation of claims 1-9.

Claim Rejections - 35 USC § 103

The rejection of claims 1-7 and 9 under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al (US Patent 6,207,184) has been withdrawn in view of Applicants cancellation of claims 1-9.

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over El Khoury (US Patent 5,994,330) has been withdrawn in view of Applicants cancellation of claims 1-9.

Newly Applied Rejections/Objections

Claim Objections

Claim 16 is objected to because of the following informalities: it appears Applicant has misspelled propylene glycol monocaprylate. Appropriate correction is required.

Claim Rejections - 35 USC § 103

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over El Khoury (US Patent 5,994,330) in view of Higo et al. (US Patent 5,932,227).

El Khoury discloses topical applications comprising muscarinic agents, such as neostigmine (column 1, lines 7-13), a lipophilic compound. Suitable topical transdermal enhancing agents include propylene glycol, sefsol (a polyol fatty acid ester) and Brij (polyoxyetheylene lauryl ether; a lauromacrogol) (column 15, lines 3-30). It is additionally disclosed combination of enhancers can lead to synergistic actions, and the determination of suitable transdermal enhancing preparations for a given use is routine in the art.

Regarding claim 11, since the prior art discloses Applicants preferred components A-C; it is the position of the examiner that it would meet the limitations of the instant claim.

Regarding claim 12, Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the permeation enhancers). However, the preparation of various sanitizing compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that

the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426(CCPA 1971).

Regarding claim 13-15, the formulation may be in the form of a gel, cream, spray, lotion, or spray (abstract).

It has been held that combinations of two or more components, all of which is taught by the prior art to be useful for the same purpose in order to form another composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since the reference teaches that propylene glycol, a polyol fatty acid ester, and a lauromacrogol are all penetration enhancers and that combining them to elicit synergistic activity is known in the art and routinely performed, it would have been obvious to combine them with the expectation that such a combination would be effective in skin care compositions. Thus, combining them flows logically from their having been individually taught in prior art.

The use of loperamide hydrochloride or lidocaine is not disclosed.

Higo discloses compositions suitable for percutaneous administration (abstract). Drug actives disclosed as being capable of percutaneous administration include lidocaine and neostigmine (column 4, lines 16-45).

It would have been obvious to one of ordinary skill in the art to have substituted one active agent for another in the transdermal composition of El-Khoury with the

expectation of achieving percutaneous/transdermal absorption since Higo discloses lidocaine and neostigmine are both known to be absorbed percutaneously. Additionally, there does not appear, and applicant has not presented any evidence of any unexpected results obtained from the particular combination of the instant claims.

Claims 10-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narui et al. (JP 10-182450) in view of Higo et al. (US Patent 5,932,227).

Narui discloses composition have excellent endermic absorption and analgesic action (abstract) comprising: 20% propylene glycol (a), 8% polyethylene glycol monoleate (b), 0.5% polyoxyethylene laurylether (c) (example 1).

The use of loperamide hydrochloride or lidocaine is not disclosed.

Higo discloses compositions suitable for percutaneous administration (abstract). Drug actives disclosed as being capable of percutaneous administration include lidocaine (column 4, lines 16-45).

It would have been obvious to one of ordinary skill in the art to have substituted one active agent for another in the transdermal composition of Narui with the expectation of achieving percutaneous/transdermal absorption since Higo discloses lidocaine is known to be absorbed percutaneously. Additionally, there does not appear, and applicant has not presented any evidence of any unexpected results obtained from the particular combination of the instant claims.

Claims 10-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi (JP 2003-093152) in view of Higo et al. (US Patent 5,932,227).

Hirabayashi discloses cosmetic sheets impregnated with a composition have efficient immigrating components from the sheet to the skin (abstract). Example 24 discloses a composition comprising 3.0% propylene glycol (a), 0.1% soribitan monostearate (b), and 0.1% polyoxyethylene lauryl ether (c).

The use of loperamide hydrochloride or lidocaine is not disclosed.

Higo discloses compositions suitable for percutaneous administration (abstract). Drug actives disclosed as being capable of percutaneous administration include lidocaine (column 4, lines 16-45).

It would have been obvious to one of ordinary skill in the art to have substituted one active agent for another in the transdermal composition of Hirabayashi with the expectation of achieving percutaneous/transdermal absorption since Higo discloses lidocaine is known to be absorbed percutaneously. Additionally, there does not appear, and applicant has not presented any evidence of any unexpected results obtained from the particular combination of the instant claims.

Claims 10-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa (JP 07-285861) in view of Higo et al. (US Patent 5,932,227).

Yanagawa discloses an external skin preparation having good percutaneous absorption (abstract). Numerous examples are disclose which comprising 2.0% propylene glycol (a), 3.0% sorbitan monostearate (b), and 2.0% polyoxyethylene lauryl ether (c).

The use of loperamide hydrochloride or lidocaine is not disclosed.

Higo discloses compositions suitable for percutaneous administration (abstract). Drug actives disclosed as being capable of percutaneous administration include lidocaine (column 4, lines 16-45).

It would have been obvious to one of ordinary skill in the art to have substituted one active agent for another in the transdermal composition of Yanagawa with the expectation of achieving percutaneous/transdermal absorption since Higo discloses lidocaine is known to be absorbed percutaneously. Additionally, there does not appear, and applicant has not presented any evidence of any unexpected results obtained from the particular combination of the instant claims.

Claim 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narui et al. (JP 10-182450) or Hirabayashi (JP 2003-093152) or Yanagawa (JP 07-285861) in view of Higo et al. (US Patent 5,932,227) and further in view of Cho et al. (US Patent 5,858,398).

The combined teachings of Narui and Higo, or Hirabayashi and Hugo, or Yanagawa and Higo are discussed above and applied in the same manner.

The references do not disclose component (b) to be from the group contained in claim 16.

Narui, Hirabayashi, and Yanagawa all disclose the use of soribitan monostearate as a surfactant.

Cho discloses surfactants suitable for use in transdermal compositions comprising substituted polyoxyethylene compounds having from 1-100 oxyethylene moieties, preferably including soribitan monocaprylate and sorbitan monostearate (column 15, line 62 through column 16, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention as made to have substituted one surfactant for the other since they are regarded as functional equivalents in the art and are both known to be used and acceptable for use in transdermal formulations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615